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| 10/532,178 | 04/21/2005 | Noam Gavriely | Tsivion P7U80 | 6763 |
| 37190 7590 01/08/2008 VARNUM, RIDDERING, SCHMIDT & HOWLETT LLP 333 BRIDGE STREET, NW P.O. BOX 352 GRAND RAPIDS, MI 49501-0352 | | | | |
| EXAMINER | | | | |
| JANG, CHRISTIAN YONGKYUN | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/532,178

Applicant(s)

GAVRIELI ET AL.

Examiner

CHRISTIAN Y. JANG

Art Unit

4153

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3, 4-5, 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 1 recites the limitation "said heart sounds" in lines 6 & 9 and "said breathing sounds" in lines 7 & 10-11. There is insufficient antecedent basis for this limitation in the claim.
4. Claim 3 recites the limitation "the respiratory activity" in line 3, and "said respiratory" in lines 4, & 5. There is insufficient antecedent basis for this limitation in the claim.
5. Claims 4-5 recites the limitation "said respiratory activity" in line 3 of claim 4, "said cardiac sounds" in lines 3-4 of claim 4 and line 3 of claim 5, "said heart sounds" in line 6 of claim 4 and line 5 of claim 5, "said breathing sounds" in lines 7-8 of claim 4 and line 7 of claim 5, and "same class r" in line 8 of claim 5. There is insufficient antecedent basis for this limitation in the claim.
6. Claim 16 recites the limitation "the synchronized heartbeat" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-3, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Shapiro et al. (USP #5,957,866).

9. **As to claim 1**, Shapiro teaches a method for analysing the functionalities of the heart and of the respiratory system of a patient (Abstract, "apparatus for assisting an operator to diagnose physical conditions in a patient"), comprising:

segmenting cyclic heart beating sounds into physically defined classes (3:47-49; "body sounds may be ... gated to the QRS complex ... or to other aspects ... such as the P and T waves") and independently segmenting cyclic breathing cycle into physiologically defined classes (3:47-48; "body sounds may be sorted according to respiratory phase");

associating segments of same class of said heart sounds with segments of same class of said breathing sounds (4:46-51; "when heart sounds ... are being analyzed, the sounds ... and respiration are detected simultaneously and analyzed as a sound ...

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because signal processor and analyzer will sort the sounds according to respiratory phase and gate the sounds using the QRS complex"), and

correlating physical characteristics of said heart sounds of same class with physical characteristics of said breathing sounds of same class (Fig. 9).

10. **As to claim 2**, Shapiro teaches a method for analyzing the functionality of the heart and the respiratory system as in claim 1, and wherein said cyclic heart beating sounds are synchronized by features of an EKG (4:46-51; "when heart sounds ... are being analyzed, ... signal processor and analyzer will ... gate the sounds using the QRS aspect of the ECG")). Examiner notes that ECG is merely another word for EKG.

11. **As to claim 3**, Shapiro teaches a method for analysing a change in the functionality of the heart and the respiratory system of a patient, comprising:

identifying the respiratory activity and cardiac sounds (3:40-42; "apparatus is provided for collection of body sounds such as heart sounds ... or breath sounds");

segmenting said respiratory and said cardiac sounds (3:47-49; "body sounds may be sorted according to respiratory phase and gated to the QRS complex ... or to other aspects ... such as the P and T waves");

classifying said segments of said respiratory and said cardiac sounds;

extracting features of said classes;

comparing the features of said classes (7:45-54; "abnormal sounds are divided into abnormal sounds, murmurs, and other extra heart sounds ... next, sounds are

classified according to their timing in the heart sound cycle ... respiratory phase is examined as a factor"), and

determining the significance of the deviation of a set of said features from a respective set of baseline values (7:54-55; "Signal processor and analyzer then suggests a lesion based upon these factors", Fig. 9).

12. **As to claim 8**, Shapiro teaches a system for monitoring the interrelated functionality of the heart and the respiratory system, comprising:

at least one means for collecting heart beating sounds (Fig. 3, 12);

means for collecting cyclic sound of the respiratory system classes (Fig. 3, 16),

and

a means for processing said sounds (Fig. 3, 30).

13. Claim 16 is rejected under 35 U.S.C. 102(e) as being anticipated by Ho et al. (US 2003/0220578).

14. **As to claim 16**, Ho teaches a method for improving magnetic resonance angiography wherein said magnetic resonance angiography acquisition time is synchronized with the synchronized heartbeat (Ho, ¶0019, "These electrodes and systems for their use particularly are useful for EKG triggering in combination with diagnostic systems that often interfere with regular EKG electrode measurements such as MRI).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro et al. (USP #5,957,866).

17. **As to claim 9**, Shapiro teaches all the limitations in the present claim except a plurality of heart sensors. However it is common in the art to use multiple sensors for the detection of same type of physiological parameter. Thus, it would have been obvious for one of ordinary skill in the art to further modify Shapiro with a plurality of sensors to increase the accuracy during use of the device.

18. Claims 4-7, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ho et al. (US 2003/0220578) in view of Shapiro et al. (USP #5,957,866).

19. **As to claim 4**, Ho teaches a method for synchronizing a heartbeat synchronized system comprising:

determining the temporal signal structure of the heart, and sending control signal to the heartbeat synchronized system (Ho, ¶0016, "invention ... enable more reliable detection of a true cardiac phase and improved cardiac gating"). Examiner notes that cardiac gating is an imaging technique used to reduce image blurring due to cardiac-induced motion.

He does not teach the following limitations, which are taught by Shapiro.

segmenting said respiratory activity and said cardiac sounds, wherein data of cardiac sounds is obtained from at least one heart sound sensor(Shapiro, 3:40-42; "apparatus is provided for collection of body sounds such as heart sounds ... or breath sounds");

correlating physical characteristics of said heart sounds of same class with physical characteristics of said breathing sounds of same class (Shapiro, 7:45-54; "abnormal sounds are divided into abnormal sounds, murmurs, and other extra heart sounds ... next, sounds are classified according to their timing in the heart sound cycle ... respiratory phase is examined as a factor");

It would have been obvious to one of ordinary skill in the art to modify Ho with the Shapiro to further incorporate respiratory-induced motion factoring to further lower image blurring and increase the accuracy of the device.

20. **As to claim 5**, Ho modified with Shapiro teaches all the limitations in the present claim except a plurality of heart sensors. However it is common in the art to use multiple sensors for the detection of same type of physiological parameter. Thus, it would have been obvious for one of ordinary skill in the art to further modify the combined teachings of Ho and Shapiro with a plurality of sensors to increase the accuracy during use of the device.

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21. **As to claim 6**, Ho teaches a diagnostic method for synchronizing a heartbeat synchronized system as in claim 4 (Ho, ¶0006, "a solution to the poor resolution problem has been to synchronize MRI signal acquisition by "gating" the MR data acquisition with the cardiac contraction cycle") Examiner notes that an MRI is capable of use for diagnostics purposes.

22. **As to claim 7**, Ho teaches a therapeutic method for synchronizing a heartbeat synchronized system as in claim 4 (Ho, ¶0019, "the invention would also improve EKG monitoring of therapeutic progress").

23. **As to claim 10**, Ho modified with Shapiro teaches a system for monitoring the interrelated functionality of the heart and the respiratory system as in claim 8 and wherein said system is a part of a heartbeat synchronized device (see rationale for claim 4)

24. **As to claim 11-15**, Ho modified with Shapiro teaches a system as in claim 10 wherein said heartbeat synchronized system is:

a monitoring device, an intra-aortic balloon pump, a left ventricular cardiac assist device, a CT coronary angiography diagnostic device, or a SPECT diagnostic device (Ho, ¶0019, "These electrodes and systems for their use particularly are useful for EKG triggering in combination with diagnostic systems that often interfere with regular EKG electrode measurements such as MRI. The invention also is useful for cardiac

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synchronization of other imaging or diagnostic studies such as cardiac nuclear scintigraphy (e.g. stress thallium, stress sestimibi, etc.), computed tomography (CT, electron beam CT, multi-detector CT, etc.), computed tomography angiography and stress echocardiography.”)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon. - Thurs. (7AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CJ
/C. Y. J./
Examiner, Art Unit 4153
12/14/07

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 4153